WORLD TRADE ORGANIZATION

G/TBT/N/BRA/1321

5 April 2022

(22-2712)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** BRAZIL **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Brazilian Health Regulatory Agency (ANVISA) **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ],3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** HS (3003-3004) - Medicaments
5.	**Title, number of pages and language(s) of the notified document:** Resolution – RDC number 625, 09 March 2022; (10 page(s), in Portuguese)
6.	**Description of content:** This resolution contains provisions on minimum requirements related to the obligation, on the part of companies holding drug market authorizations, to communicate the implementation of the action of recalling drugs to the competent health authorities and consumers, in the event of sufficient evidence or proof of quality deviation that represent a risk, aggravation or health consequences, as well as in the event of deregistration related to safety and efficacy.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety
8.	**Relevant documents:** -
9.	**Proposed date of adoption:** 1 April 2022 **Proposed date of entry into force:** 1 April 2022
10.	**Final date for comments:** Not applied

11. Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Brazilian Health Regulatory Agency (Anvisa)SIA, Trecho 5, Área Especial 57
Brasília – DF / Brazil
Zip Code: 71.205-050
Phone.: +(55) 61 3462.5402
Website: www.anvisa.gov.br

http://antigo.anvisa.gov.br/documents/10181/6407711/RDC_625_2022_.pdf/3413d4ad-5043-4920-bb8e-5391a0a360e8